Safety and effectiveness as required by 21 CFR 807.92

This summary of the 510K Safety and effectiveness information is being submitted in accordance with the requirements 21 CFR 807.92

DEC 16 2013

1A. 510(k) Number: K132688

Date of revised Summary Preparation

December 11, 2013

B. Purpose for Submission:

New Device (Traditional 510K)

2. Submitter name and address:

Biochemical Diagnostics, Inc.
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Edgewood, NY 11717
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SBD #126040

Contact Person

Allen
Panetz,
President
Phone: 631-595-9200 Ext. 3011

3. Proprietary and Established Names:

Product trade name: Salivabuse® Liquid Oral Fluid Control

Established Names Include:

Salivabuse® Liquid Control Oral

Fluid Salivabuse® Liquid Control

Oral Fluid, AU/NZ

4. Regulatory Information:

Classification name: Clinical Toxicology Control Material

Product Code	Classification	Regulation Section	Panel
DIF	Class I, reserved	21 CFR 862.3280	Toxicology

5. Substantial Equivalence Information:

1. **Predicate device A**	Predicate K number
Oratect®Check Saliva/Oral Fluid Controls (Positive and Negative)	K103227

6a. Device Description:

The Salivabuse ® multi-constituent and the Salivabuse® single constituent controls are designed to provide an estimation of the precision of a device test system, and to detect and monitor systematic deviations from accuracy resulting from reagent or instrument defects. Salivabuse® liquid oral fluid controls are available in Negative, Cutoff -60%, Cutoff -50%, Cutoff -30%, Cutoff -25%, Cutoff, Cutoff +25%, Cutoff +50%, 2X Cutoff and 3X Cutoff levels. Each bottle contains stabilized synthetic oral fluid. Positive controls have been gravimetrically spiked with authentic reference drug standards and/or appropriate metabolites. Negative controls are certified negative by combination of immunoassay, GC/MS and/or LC/MS for the constituents listed on our target sheets. The products contain either sodium azide or a proprietary preservative compatible with products that are adversely affected by sodium azide.

b. Measurand:

Quality control material for Oral Fluid testing of Amphetamines, Methamphetamines, Cocaine, Benzoylecgonine, Opiates, PCP, Cannabinoids, Barbiturates, Benzodiazepines, Methadone, Cotinine, and Ethanol

7. Intended Use:

The Salivabuse® liquid oral fluid controls are intended for *in vitro* diagnostic use only as quality controls to monitor the precision of laboratory oral fluid toxicology testing procedures for the analytes listed in the package insert. The Salivabuse ® controls are available as multi-constituent and single constituent controls.

8. Special conditions for use statement:

Salivabuse® liquid oral fluid controls have been designed for in vitro diagnostic use only. They should not be pipetted by mouth and the normal precautions for handling laboratory specimens should be applied. The products contain either sodium azide or a proprietary preservative compatible with products that are adversely affected by sodium azide.

9. Special instrument requirements: None

10. Comparison of Technological Characteristics

Similarities and differences between new and predicate devices.

Similarities		
Device	**Predicate Device (K103227)** Oratect®Check Saliva/Oral Fluid Controls (Positive and Negative)	**New Device (K132688)** Salivabuse® Liquid Oral Fluid Control
Intended Use	Quality control oral fluid to monitor the performance of laboratory toxicology screening procedures. For in vitro diagnostic use only	Quality control oral fluid to monitor the performance of laboratory toxicology screening procedures. For in vitro diagnostic use only
Form	Liquid	Liquid
Differences		
Target Drug Levels **(See package inserts)**	Negative, Cutoff, Cutoff +50%, Cutoff -50%,	Negative, Cutoff -60%, Cutoff +/-50%, -30%, Cutoff +/-25%, Cutoff, 2X Cutoff, 3X Cutoff
Matrix	Synthetic oral fluid	Stabilized synthetic oral fluid.
Storage **Unopened**	**Unopened** The controls are stable until the expiration date (24 months) when stored at -15°C.	**Unopened** **The controls are stable until the expiration date (12 months) when stored -10°C to -20°C (frozen) or 2°-8°C (refrigerated).**
Storage **Opened**	**Opened** The opened vial controls are stable for 7 days stored at 4°C.	The opened vial controls are stable for 31 days stored at 2-8°C.

Analytes	Amphetamines(Amphetamine), Methamphetamines(Methamphetamine), Cocaine, Benzoylecgonine, Opiates, PCP, Cannabinoids(THC)	**The same measurands from predicate device K103227 with the additional measurands:** Methadone , Cotinine Ethanol, Benzodiazepines Barbiturates

Performance validation studies were conducted using the following methods:

1) **GC/MS**
2) **LC/MS**
3) **Immunoassay Screening (immunoassay analyzers and/or immunoassay single use screening devices)**

11. Summary of Stability Studies

Stability Protocol:

As part of our ongoing Quality System, Biochemical Diagnostics performs real time and accelerated stability testing on our controls to verify the performance claims in our package inserts.

Multi-Constituent controls were tested, Refrigerated (2-8°C), and Frozen (-10 to -20°C). Unopened controls are tested at Time "0" and then repeated on freshly opened vials at the end point of study. Opened vial study was conducted by opening vials to remove an aliquot of control to simulate customer usage and sampling the same vial at the end point of the study. At least 3 different vials from three different lots are tested for each temperature condition.

Protocol - Open Vial (2-8°C)
Stability

Multiple bottles from three lots of individual or multi-constituent Salivabuse® controls were pulled from beginning, middle, and end of production, set aside, and unopened bottles were assayed at time of manufacturing and opened bottles again tested at 31 days.

Protocol - Closed Vial (2-8°C)
Stability

Multiple bottles from three of individual or multi-constituent Salivabuse® controls were pulled from beginning, middle, and end of production , set aside and unopened bottles were assayed at time of manufacturing and again periodically. Studies are ongoing and sent for assay until expiration date. Refrigerated temperature on unopened vial Salivabuse® controls was sampled and tested at peroiodically for one year for drugs listed in submission, studies ongoing.

Protocol - Closed Vial (-10°C to -20°C)
Stability

Multiple bottles from three lots of individual or multi-constituent Salivabuse® controls were pulled from beginning, middle, and end of production , set aside and frozen within a temperature range of -10°C to -20°C. Unopened bottles were sampled and tested at periodically for the first year for, drugs listed in submission, studies ongoing.

Stability Summary Table:

Evaluation Parameter for Stability of Product Shelf Life (Temperature) (Open/Closed Vial)	**Specifications for Real time study.** 1. # of vials tests 2. length of study 3. Conclusion	**Acceptance Criteria** Positive controls test positive and Negative controls test negative. **Results:** Pass / Fail
Refrigerated Temperature (2-8°C) (Open Bottle)	**1.** 3 lots/3 vials each tested **2.** T-0, 31 days. **3.** Positive controls tested positive and Negative controls tested negative.	PASS
Refrigerated Temperature (2-8°C) (Close Bottle)	**1.** 3 lots/3 vials each tested for the drugs listed in submission periodically for 1 year, study ongoing. Positive controls tested positive and Negative controls tested negative.	PASS
Frozen Temperature (-10°C to -20°C) (Close vial)	**1.** 3 lots/3 vials each tested for the drugs listed in submission periodically for 1 year, study ongoing. Positive controls tested positive and Negative controls tested Negative.	PASS

Conclusions

Protocol - Open Vial (2-8°C) Stability
Conclusion:

Data supports the 31-day open bottle stability claim at 2-8°C for all analytes in the lots evaluated. All analytes tested passed specifications, Positive controls tested positive and Negative controls tested negative

Protocol - Closed Vial (2-8°C) Stability

Conclusion:

All analytes tested passed specifications, Positive controls tested positive and Negative controls tested negative for 1 year for the drugs listed in submission(study ongoing).

Protocol - Closed Vial (-10°C to -20°C) Stability

Conclusion:

Multiple studies were conducted using several different lots. All analytes tested passed specifications, Positive controls tested positive and Negative controls tested negative for 1 year for drugs listed in submission (studies ongoing).

12. Summary of Value Assignment

The following procedure is used for value assignment

a. Assay Methodology used to assign values:
Certified Independent laboratories using the following test methods: GC/MS, LC/MS, Immunoassay analyzers, and single-use FDA cleared drugs of abuse screening devices were used for value assignment to ensure control solutions contain appropriate analyte levels.

b. Value assignment Criteria:
An initial production batch is sampled from the beginning, middle and end of production. Single or multiple samples were analyzed by quantitative GC/MS and/or LC/MS (using SAMHSA licensed laboratories or CAP inspected and certified laboratories), and immunoassay analyzers. The Salivabuse® controls were also tested on single-use FDA cleared drugs of abuse screening devices from several manufacturers. Acceptance criteria for immunoassay and single-use devices was that positive controls test positive and negative product tests negative.

Acceptance criteria for GC/MS or LC/MS at the end of its expiration date was that analytes were within ± 20% of target value. All analytes met the acceptance criteria for the Salivabuse® controls.

13. Traceability

The controls are manufactured using reference standards supplied by commercial vendors. Accuracy is certified by purity determination using analytical tools including GC/MS, LC/MS, or NMR. Gravimetric preparation is accomplished using balances calibrated with weights that are traceable to National Institute of Standards and Technology (NIST).

14. Conclusion

Testing results indicate that the proposed device is substantially equivalent to the Predicate device Oratect®Check Saliva/Oral Fluid Controls K103227 (Positive and Negative) with the additional measurands: Methadone, Cotinine, Ethanol, Benzodiazepines and Barbiturates.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

December 16, 2013

BIOCHEMICAL DIAGNOSTICS, INC.
ALLEN PANETZ
PRESIDENT
180 HEARTLAND BLVD.
EDGEWOOD NY 11717

Re: K132688
Trade/Device Name: Salivabuse® Liquid Oral Fluid Control
Regulation Number: 21 CFR 862.3280
Regulation Name: Clinical toxicology control material
Regulatory Class: I, reserved
Product Code: DIF
Dated: November 1, 2013
Received: November 8, 2013

Dear Mr. Panetz:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Carol C. Benson -S for

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See *PRA Statement on last page.*

510(k) Number *(if known)*
k132688

Device Name
Salivabuse Liquid Oral Fluid Control

Indications for Use *(Describe)*
The Salivabuse® liquid oral fluid controls are intended for *in vitro* diagnostic use only as quality controls to monitor the precision of laboratory oral fluid toxicology testing procedures for the analytes listed in the package insert. The Salivabuse ® controls are available as multi-constituent and single constituent controls.

Type of Use *(Select one or both, as applicable)*

[X] Prescription Use (Part 21 CFR 801 Subpart D) O Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Denise Johnson-lyles -S